

**REMARKS**

Applicants acknowledge receipt of the Office Action mailed March 3, 2009.

In the Office Action, the Examiner rejected claims 75 and 90-101 under 35 U.S.C. § 102(b) as being anticipated by *Richards et al.* (U.S. Patent No. 6,296,809); rejected claims 102-113, 116-118, 120, and 121 under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Ammann et al.* (U.S. Patent Pub. No. 2005/0233370); rejected claims 75 and 90-101 under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Kalra et al.* (U.S. Patent No. 6,495,106); rejected claims 102-113, 116-118, 120, and 121 under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Ammann* and *Kalra*; rejected claim 114 under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Kalra*, and further in view of *Gonska et al.* (U.S. Patent No. 6,568,770); and rejected claims 115 and 119 under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Amman* and *Kalra*, and further in view of *Gonska*.

By this Amendment, Applicants amend claims 75, 102, and 118. Claims 75 and 90-121 remain pending. Of these claims, claims 75, 102, and 118 are independent.

Applicants traverse the rejections above and respectfully request reconsideration for at least the reasons that follow.

**I. 35 U.S.C. § 102(b) REJECTION**

Applicants traverse the rejection of claims 75 and 90-101 under 35 U.S.C. § 102(b) as being anticipated by *Richards*.

In order to properly establish that *Richards* anticipates Applicants' claimed invention under 35 U.S.C. § 102, each and every element of each of the claims in issue

must be found, either expressly described or under principles of inherency, in that single reference (emphases added). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." See M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

*Richards* appears to disclose an apparatus and method for automatically staining or treating multiple tissue samples mounted on microscope slides. Individualized slide temperature control is accomplished by a heating system 48, which includes thermal platforms radially mounted to a carousel for heating the slides and sensing the temperature of each. (*Richards*, Abstract).

As admitted by the Examiner, "Richards does not expressly teach that sample slides are inserted or removed during processing without interrupting the processing of other samples. Richards is largely silent on the matter." (*Office Action*, p. 11, ll. 8-10). The Examiner further states, "the Richards apparatus is considered to be fully capable of being operated in this way. Since each slide (37) is independently and removably mounted over a different thermal platform (50) . . . , it is understood that each slide may be inserted or removed during the processing protocol without interrupting a processing of another sample." (*Id.* at p. 11, ll. 11-15). Applicants respectfully disagree.

Although *Richards* discloses a slide carousel 34 with a plurality of thermal platforms 50, upon which glass slides with tissue samples may be placed, and where the temperature of each slide may be individually controlled by means of various sensors and microprocessors (*Richards*, col. 5, line 65 - col. 6, line 6), such teaching does not suggest that each slide may be inserted or removed during a processing

protocol without interrupting a processing of another sample. In fact, *Richards* discloses that

Typical In-Situ Hybridization (ISH), In-Situ PCR, Immunohistochemical (IHC), Histochemical (HC), or Enzymehistochemical (EHC) methods as carried out with the apparatus of this invention includes the following steps.

- 1) Slides are prepared by applying a bar code to the slide indicating the In-Situ Hybridization, In-Situ PCR Immunohistochemical, Histochemical, or Enzymehistochemical process to be used with the sample.
- 2) Inserting a batch of slides in the apparatus, mounting each slide into a slide support.
- 3) Closing the apparatus and beginning the treatment process. (Col 16, ll. 17-28)

Clearly, *Richards* teaches that "a batch of slides" is inserted prior to beginning the treatment process. There is no disclosure of inserting or removing any slide during the processing of another slide.

*Richards* further teaches that

[f]or each slide, a single reagent is applied and then incubated for a precise period of time in a temperature-controlled environment . . . After the appropriate incubation, the reagent is washed off the slide using nozzles 36. Then the remaining wash buffer volume is adjusted using the volume adjust nozzle 39. Coverslip<sup>TM</sup> solution, to inhibit evaporation, is then applied to the slide via nozzle 37. Air knife 38 divides the pool of Coverslip<sup>TM</sup> followed by the application of the next reagent. These steps are repeated as the carousels turn until the protocol is completed. (Col. 6, ll. 21-33)

Accordingly, *Richards* teaches away from inserting or removing slides during a processing protocol, as a specific sequence of steps are carried out for each of the

slides until the protocol is completed. Insertion or removal of a slide during the protocol would interrupt the processing of another sample and disrupt the protocol.

Accordingly, *Richards* fails to teach or suggest an automated sample processing system "wherein [a] carrier is inserted or removed during [a] processing protocol without interrupting a processing of another sample," as required by claim 75.

Since the Examiner admits that each and every element of independent claim 75 is not found in *Richards*, either expressly or under principles of inherency, the rejection of claim 75, and claims 90-101 which depend therefrom, is improper. Therefore, Applicants respectfully request that this rejection be withdrawn.

## II. 35 U.S.C. § 103(a) REJECTIONS

Claims 102-113, 116-118, 120, and 121 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Ammann*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that independent claims 102 and 118 distinguish over *Richards* and *Ammann* at least for the reasons described below.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 6 (Sept. 2007). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See Id. "[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art." M.P.E.P.

§ 2141(II). "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." M.P.E.P. § 2141(III).

As discussed above, *Richards* appears to disclose an apparatus and method for automatically staining or treating multiple tissue samples mounted on microscope slides. Individualized slide temperature control is accomplished by a heating system 48, which includes thermal platforms radially mounted to a carousel, for heating the slides and sensing the temperature of each. (*Richards*, Abstract).

As admitted by the Examiner, "Richards...does not expressly disclose that reagent temperature control elements are provided for regulating the temperature of reagents before they are applied to the sample." (*Office Action*, p. 5, ll. 8-10). Furthermore, as reiterated above, *Richards* also fails to disclose or suggest "wherein [a] carrier is inserted or removed during [a] processing protocol without interrupting a processing of another sample," as recited in claims 102 and 118.

In order to cure the deficiencies of *Richards*, the Examiner relies on *Ammann* and alleges "Ammann teaches that thermoelectric modules and fan units provide the desired cooling capacity, and are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers." (*Office Action*, p. 5, ll. 16-18). Such teaching, even if disclosed in *Ammann*, which Applicants do not necessarily concede, however, fails to teach or suggest, "wherein [a] carrier is inserted or removed during [a] processing protocol without interrupting a processing of another sample," as recited in claims 102 and 118. Thus, *Ammann* also fails to overcome the above noted shortcomings of *Richards*.

In fact, *Ammann* teaches away from the claimed limitation recited in claims 102 and 118. *Ammann* discloses that

[a] plurality of reaction receptacles are loaded in a stacked fashion in the input queue 150. . . . A reaction receptacle shuttle assembly . . . within the queue moves the receptacles along a receptacle advance path toward the pick-up position. . . . The queue includes a drawer which may be pulled out for loading the receptacles therein. Before the drawer is opened, however, it must be unlocked and the shuttle must disengage from the receptacle advance path. When the drawer is again closed, it is locked and the shuttle engages the receptacles and moves them toward the pick-up position. (*Ammann*, paras. [0106] - [0107]).

Accordingly, a processing of a reaction receptacle is interrupted when additional reaction receptacles are inserted during a processing protocol, as the drawer which loads the receptacles therein must be unlocked and the reaction receptacle shuttle assembly must disengage from the receptacle advance path before additional reaction receptacles are added.

As explained above, the elements of independent claims 102 and 118 are neither taught nor suggested by the cited references and no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claims 102 and 118, and claims 103-113, 116, 117, 120, and 121 which correspondingly depend from claims 102 and 118. Claims 102-113, 116-118, 120, and 121 are therefore patentable over *Richards* and *Ammann*, and Applicants respectfully request that this rejection be withdrawn.

Claims 75 and 90-101 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Kalra*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that independent claim 75 distinguishes over *Richards* and *Kalra* at least for the reasons described below. The deficiencies of *Richards* are discussed above.

With respect to *Kalra*, the Examiner alleges, "the *Kalra* reference has been provided as evidence that it is known in the art to insert/remove a sample carrier during processing without interrupting the processing of other samples." (*Office Action*, p. 7, ll. 11-13). Applicants respectfully disagree.

*Kalra* appears to disclose an automated staining apparatus including an arm 30 moveable in three dimensions, and a hollow tip head 70 located on the arm 30 including an integral reagent tip head 40, a wash tip 41 and a blow tip 42 for selectively dispensing gas and liquid onto microscope slides. (*Kalra*, Abstract).

*Kalra*, however, fails to teach or suggest an automated sample processing system "wherein [a] carrier is inserted or removed during [a] processing protocol without interrupting a processing of another sample," as required by claim 75.

The Examiner alleges, "[c]olumn 17, lines 54-61 states that slides can be removed from the system without interrupting the processing of remaining slides." (*Office Action*, p. 7, ll. 16-17). The cited passage of *Kalra*, however, refers to a batch-processing method used in bar-code reading. *Kalra* discloses that rather than reading the bar-codes and acting on the information individually, the laser scanner 410 scans the bar-codes by batch in order to increase processing speed. (*Kalra*, col. 17, ll. 17-22). The batch-processing method in *Kalra*, however, is devised to occur before a sample is

processed on a slide. Accordingly, *Kalra* does not disclose inserting or removing a slide during a processing protocol without interrupting a processing of another sample, since the processing of samples on the slides has not yet begun. Therefore, *Kalra* also fails to overcome the above noted shortcomings of *Richards*.

As explained above, the elements of independent claim 75 are neither taught nor suggested by the cited references and no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 75, and claims 90-101 which depend from claim 75. Claims 75 and 90-101 are therefore patentable over *Richards* and *Kalra*, and Applicants respectfully request that this rejection be withdrawn.

Claims 102-113, 116-118, 120, and 121 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Ammann* and *Kalra*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that independent claims 102 and 118 distinguish over *Richards*, *Ammann*, and *Kalra* at least for the reasons described below.

As discussed above, *Richards* appears to disclose an apparatus and method for automatically staining or treating multiple tissue samples mounted on microscope slides. Individualized slide temperature control is accomplished by a heating system 48, which includes thermal platforms radially mounted to a carousel, for heating the slides and sensing the temperature of each. (*Richards*, Abstract).



As admitted by the Examiner, "Richards...does not expressly disclose that reagent temperature control elements are provided for regulating the temperature of reagents before they are applied to the sample." (*Office Action*, p. 5, ll. 8-10). Furthermore, as reiterated above, *Richards* also fails to disclose or suggest "wherein [a] carrier is inserted or removed during [a] processing protocol without interrupting a processing of another sample," as recited in claims 102 and 118.

In order to cure the deficiencies of *Richards*, the Examiner relies on *Ammann* and *Kalra* and alleges "Ammann teaches that thermoelectric modules and fan units provide the desired cooling capacity, and are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers" (*Office Action*, p. 5, ll. 16-18), and "[c]olumn 17, lines 54-61 [of *Kalra*] states that slides can be removed from the system without interrupting the processing of remaining slides" (*Id.* at p. 8, ll. 14-15).

As explained above, such teachings, even if disclosed in *Ammann* and *Kalra*, which Applicants do not necessarily concede, however, fail to teach or suggest, "wherein [a] carrier is inserted or removed during [a] processing protocol without interrupting a processing of another sample," as recited in claims 102 and 118. Thus, *Ammann* and *Kalra* also fail to overcome the above noted shortcomings of *Richards*.

As explained above, the elements of independent claims 102 and 118 are neither taught nor suggested by the cited references and no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claims 102 and 118, and claims 103-113, 116, 117, 120, and 121, which correspondingly depend from claims 102 and 118. Claims 102-113, 116-118, 120, and

121 are therefore patentable over *Richards*, *Ammann*, and *Kalra*. Applicants respectfully request that this rejection be withdrawn.

Claim 114 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Kalra*, and further in view of *Gonska*; and claims 115 and 119 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Richards* in view of *Amman* and *Kalra*, and further in view of *Gonska*. The deficiencies of *Richards*, *Kalra*, and *Amman* are discussed above.

With respect to *Gonska*, the Examiner asserts, "Gonska discloses an automated system for handling various biological sample carriers . . . A plurality of drawers . . . are provided for storing the sample carriers in a controlled environment . . ." (*Office Action*, p. 9, ll. 9-11). Such teaching, even if present in *Gonska*, which Applicants do not concede, however, fails to teach or suggest, "wherein [a] carrier is inserted or removed during [a] processing protocol without interrupting a processing of another sample," as recited in independent claims 75, 102, and 118. Accordingly, claims 114, 115, and 119 are in condition for allowance at least due to their corresponding dependence from claims 75, 102, and 118. Applicants therefore request that the rejection of claims 114, 115, and 119 under 35 U.S.C. § 103(a) be withdrawn.

### III. CONCLUSION

Applicants respectfully submit that claims 75 and 90-121 are in condition for allowance.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: June 3, 2009

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